IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

K. Kristensen,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 3:09-CV-00084
	)	Consolidated
William David Spotnitz, et al.	)	
	)	
Defendants.	)	
_____	)	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION IN LIMINE TO EXCLUDE PLAINTIFFS' EXPERTS

Defendants have filed a motion to exclude the expert opinions of Plaintiffs' two non-medical experts, Dr. Vance and Dr. Lipsey, two medical treating experts Drs. Frye and Elgort, and one medical expert Dr. Joseph Vilseck, all of whose proposed testimony Defendants assert is "unreliable, unfounded and irrelevant" under *Daubert v. Merrell Dow Pharms*, 509 U.S. 579, 592-93 (1993) and Federal Rules of Evidence § 702. Predicated on the Motion in Limine, Defendants ask the Court to grant summary judgment if all of the experts are excluded.

Defendants' motion alleges that a lack of evidence, lack of literature support, or a lack of "dose response" relationship fail to meet *Daubert* requirements. Consistent with all 4th Circuit holdings, Plaintiffs' experts' opinions are adequately supported by the evidence and virtually every *published and peer reviewed* governmental and medical literature source, as opposed to unpublished "position papers" written by hired insurance defense experts who ignore nearly all reputable government or treatise peer-reviewed national publications. Defendants' experts may argue that "dose response" is necessary for mold and damp indoor space causation, but their

opinion is not followed by national medical or toxicological peer reviewed literature which rejects any concept of "dose response" for damp indoor space exposures.

BACKGROUND

Plaintiffs are two minor children who sue by their next friend and Mother. The children claim injuries and emotional distress because of their exposure to mold and excessive moisture conditions, i.e., a damp indoor space, in a home where they were made ill, suffered the loss of all belongings and its accompanying emotional distress, compounded by the emotional distress of young children facing the complete disabling injuries of the Mother, and then an ultimate bitter divorce.[1]

Dr. Vilseck is a 40 year experienced clinical allergist and pulmonary doctor who is serving as the medical expert for the Plaintiff children, and who renders expert opinions as to general and specific causation for the children.

Dr. Leonard Vance, PhD and engineer, is an industrial hygienist and professor at Virginia Commonwealth University, who appears as an expert in mold investigation and damp indoor spaces, and who teaches same at VCU. Dr. Vance offers opinions on basic mold and moisture industrial hygiene, sampling and home conditions as relates to mold and damp indoor spaces.

Dr. Lipsey is a senior toxicologist, with specialized experience and training in fungal toxicology, who opines as to the toxicology of mold exposures and their capability to cause illness.

Dr. Frye is a treating doctor, who treated the two children and family members during the

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[1]/ The emotional distress to A. Kristensen was caused by the illness and subsequent loss of belongings and family turmoil, according to Plaintiffs' expert child psychiatrist and treating doctor Anthony Poehailos, who is not a subject of any motion to exclude.

time of their exposures in the subject home, and who rendered a traditional differential diagnosis of mold causation and/or aggravation.

Finally, Dr. Elgort is a licensed clinical psychologist who offers a diagnosis of adjustment disorder in K. K., and testimony concerning the nature of her adjustment disorder and mental health in 2008.

STANDARD OF REVIEW

As courts in this circuit have recognized, the U.S. Supreme Court's ruling in *Daubert v. Merrell Dow Pharm., Inc*. 509 U.S. 579 (1993) was a liberalization, not a tightening, of the rules controlling admission of expert testimony. *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996). "The *Daubert* Court held that two questions control admission of scientific expert testimony: whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology can be applied to the facts in issue." *Id.* To make these determinations, the court uses a "flexible inquiry" based on five factors: (1) whether the testimony has been tested, (2) whether it has been published or exposed to peer review, (3) its rate of error, (4) whether there are standards and controls over its implementation, and (5) whether it is generally excepted. *Id*. *Cavallo* emphasizes that "exclusion is the least favored means of rendering questionable scientific evidence ineffective." *Id.* In reviewing the *Cavallo* district court decision, the 4th Circuit held:

> Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. Additionally, in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, and likewise to grant summary judgment. These conventional devices, rather than wholesale exclusion

> under an uncompromising "general acceptance" test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702.

Cavallo v. Star Enterprise, 100 F.3d 1150, 1158-1159 (4th Cir. 1996) (citing *Daubert* at 595-97).

Contrary to Defendants' assertion, not every exposure is subject to a standard of review for a dose response relationship. While chemical exposures are more susceptible to such analysis, complex biological agent exposures are not. In viewing this kind of evaluation, the Fourth Circuit has held:

> [o]nly rarely are humans exposed to chemicals in a manner that permits a quantitative determination of adverse outcomes. . . . Human exposure occurs most frequently in occupational settings where workers are exposed to industrial chemicals like lead or asbestos; however, even under these circumstances, it is usually difficult, if not impossible, to quantify the amount of exposure. Citing Federal Judicial Center, *Reference Manual on Scientific Evidence* 187 (1994).
>
> Consequently, while precise information concerning the exposure necessary to cause specific harm to humans and exact details pertaining to the plaintiff's exposure are beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic to humans given substantial exposure and need not invariably provide the basis for an expert's opinion on causation. . . *See Heller*, 167 F.3d at 157 (noting "that even absent hard evidence of the level of exposure to the chemical in question, a medical expert could offer an opinion that the chemical caused plaintiff's illness").

Westberry v. Gislaved Gummi AB, 178 F.3d 257, 264 (4th Cir. 1999).

Other courts are in agreement:

> [S]ome fields have not yet yielded a quantifiable threshold level of harmful exposure for certain agents, or a "dose/response relationship" supportive of specific causation. . . . When a sound differential diagnosis has been performed, the need for evidence of threshold levels is obviated. Also, we recognized that only rarely are humans exposed to chemicals in a manner that permits a quantitative determination of adverse outcomes. . .Such evidence is not always available, or necessary, to demonstrate that a substance is toxic to humans given substantial exposures and need not invariably provide the basis for an expert's opinion on causation. *Citing Westberry v. Gislaved Gummi AB* (C.A. 4, 1999).

Terry v. Ottowa County Board, 165 Ohio App. 3d 638, 656-657 (2006), *rev'd in part on other grounds, aff'd in part,* 115 Ohio St. 3d 351, 875 N.E.2d 72 (Ohio 2007) (Applying *Daubert*).

Two experts in this case are treating doctors who render opinions based on a differential diagnosis. In this Circuit, such diagnosis is considered particularly worthy of admission, and does not require the degree of external support traditionally applied to pure expert testimony:

> Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated. . . . A reliable differential diagnosis typically, though not invariably, is performed after "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely. . . [citing] *Glaser v. Thompson Med. Co.*, 32 F.3d 969, 978 (6th Cir. 1994) (recognizing that differential diagnosis is "a standard diagnostic tool used by medical professionals to diagnose the most likely cause or causes of illness, injury and disease"). This technique "has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results." . . . *see Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 154-55 (3d Cir. [F.3d 263] 1999) (noting "that differential diagnosis consists of a testable hypothesis, has been peer reviewed, contains standards for controlling its operation, is generally accepted, and is used outside of the judicial context" (internal quotation marks omitted)). We previously have upheld the admission of an expert opinion on causation based upon a differential diagnosis. *See Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383-85 (4th Cir. 1995) (holding that expert testimony by treating physician concerning cause of plaintiff's liver failure — acetaminophen combined with alcohol — was admissible despite the lack of epidemiological data). And, the overwhelming majority of the courts of appeals that have addressed the issue have held that a medical opinion on causation based upon a reliable differential diagnosis is sufficiently valid to satisfy the first prong of the Rule 702 inquiry. . . Thus, we hold that a reliable differential diagnosis provides a valid foundation for an expert opinion (citations omitted).

Westberry v. Gislaved Gummi AB, 178 F.3d at 262-263.

Finally, some experts also consider and rely upon the temporal relationship of the children's illness with that of the parents in the home, and the similarity of symptoms and timing.

As stated in *Westberry:*

> [T]he mere fact that two events correspond in time does not mean that the two necessarily are related in any causative fashion. . . . But, depending on the circumstances, a temporal relationship between exposure to a substance and the onset of a disease or a worsening of symptoms can provide compelling evidence of causation. . . .

Westberry at 265.

Applying these established standards for *Daubert* review in this Circuit, Plaintiffs respond to the individual arguments in the order presented by the Defendants.

DR. VANCE APPLIES WELL ESTABLISHED METHODS AND DATA APPLICABLE TO THIS CASE AND VIRGINIA LAW

Dr. Vance is a professor in industrial hygiene at Virginia Commonwealth University. He holds a PHD in chemistry, a J.D., is a licensed professional engineer, and is board certified in industrial hygiene. *See*, Vance resume, Exhibit 1 (also filed with designation). His role as an industrial hygiene expert in this case is to present expert opinion on the mold investigation at the subject home, interpretation of sampling and lab data, exposures to damp indoor spaces, and the factors involved in such exposures. The role of the industrial hygienist in both industrial and other health risk evaluations is unquestioned; Defendants cite no authority against qualified industrial hygiene testimony under *Daubert.*

Defendants assert that Dr. Vance should be excluded because (1) there are no national or industrial hygiene standards for mold exposure, and thus Dr. Vance cannot identify to the court the specific level of exposures suffered by the children in the home; (2) mold is everywhere, and there is insufficient showing of excessive mold in this home; (3) the testimony on mold mycotoxins should be excluded for the same reason as mold, i.e, no standards; (4) the testimony

on mold volatile organic compounds (VOCs) should be excluded for the same reason as mold, i.e, no standards; and (5) Dr. Vance renders improper medical causation opinions.

It is testified by both Dr. Vance (CIH) and Dr. Lipsey (toxicologist) that no national standards for "safe" levels of mold exposure exist (Vance T. 15:13-17), and no one disputes that fact. Nonetheless, there are standards for when mold requires remediation and why, and when molds and damp indoor spaces present a health threat and these will be addressed below. It is the national consensus of governmental, national and international independent medical entities that no exposure standards are possible for mold exposures, and in particular, to the mix of molds, bacteria, VOCs, microbial by-products and mycotoxins that are known to exist in a damp indoor space.[2] These are biological exposures to an individual person's immune system, and the mix of exposures combined with individual sensitivity, and the state of allergic reactions existing or created in each individual is too complex for any standard. For these reasons, government entities and the national literature have relied on the presence of excessive moisture in an indoor space, combined with the presence of visible mold, to affirm a potential health hazard, and the presence of all products of such excessive moisture and mold, which include bacterial growths, VOCs and mycotoxins. These conditions now produce a condition that is inescapably mold caused, a "damp indoor space" (see WHO report below).

Dr. Vance relies on the professional standards and guidance in his field. Vance, T. 5:20-25; 6:1-5. The first comprehensive treatise on microbial growth and excessive moisture

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[2]/ It is beyond the page limits of this brief to quote from every relevant document on this subject. Copies of relevant governmental and scientific treaties and published papers are or have been provided to the Court as Exhibits, and specific quotes for each issue are included in the notes herein.

conditions was published by the American Conference of Governmental Industrial Hygienists ("ACGIH") in 1999.[3] *See*, Exhibit 2. Now referred to as the "bible" of industrial hygiene on mold, the ACGIH document applies to all "bioaersols," a term embracing all microscopic microbials and particles which may be airborne in a building, which include mold, microbial by-products, VOCs and mycotoxins. According to ACGIH "many fungi produce allergens and some fungi produce toxins. Fungal growth in buildings is undesirable and may cause health problems for building occupants." ACGIH at § 7.4.2. This is the classic testimony of all industrial hygiene experts, and Dr. Vance found excessive levels of visible mold in this unit. Vance, T.11:8-22. ACGIH reports that "[c]hronic flooding or leaks will almost always result in microbial growth in the indoor environment. Fungi have been shown to be capable of germination, growth and sporulation [release of spores] in as little as 24 hours after water damage occurs." ACGIH at § 10.4.1. Again, Dr. Vance's opinion as to mold growth associated with water damage is consistent with ACGIH, as well as other treatises (see below), and follows the methods used n his profession and outlined in the ACGIH manual. Vance, T. 11:13-25; 12:1-25; 13:1-25; 14:1-15.

As to the use of observational data by Dr. Vance, ACGIH states:

> An investigator can use observational data to estimate the likelihood that bioaersols [i.e., mold, VOCs, and mycotoxins] would be generated, that workers would inhale the material, and that exposure would be sufficient to cause an adverse health effect or predispose a person to one . . . Presence of a potential source does indicate increased risks of exposure and adverse health effects . . . Microbial growth in occupied interiors . . . and on building materials should not

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[3]/ American Conference of Governmental Industrial Hygienists, Bioaersols, Assessment and Control (1999).

Each of the treatise and national documents referenced in this brief are attached as exhibits and/or filed on disc with the court.

be allowed and such contamination should be removed and further contamination should be prevented."

ACGIH , § 14.2.1.

Visible mold is an entirely different concept from the fact that "invisible" mold, in the form of microscopic spores, is ubiquitous in the environment. Mold spores in the natural environment are microscopic and invisible to the unaided eye; such spores occur outside, inside and everywhere. However, the ubiquitous nature of mold ends when a mold spore settles on a damp indoor space, where the spore can reproduce and become a mold "colony." A mold colony is composed of millions of spores, and it is the mold "colony" that become visible to the naked eye. The growth of mold colonies indoors, often called visible mold, is a product of excessive moisture conditions and can lead to health problems. ACGIH, §§ 1.1 (biological agents indoors are contaminates); 4.4.3 (water damaged materials support mold growth); 10.4.1 (leaks result in mold growth); 10.3.1 (water damage, not humidity, is causative of mold growth); 10.4.4.5 (moisture accumulation creates the environment for microbial growth). Every single governmental and national scientific or medical treatise recognizes that "visible mold" is the criteria for potential health risk and the need for immediate remediation, and this fact is repeatedly referenced herein. Dr. Vance stated that the "standard" for all governmental entities is "visible mold." Vance, T. 41:25; 42:1-4.

Indeed, of the few guidelines/standards that do exist, the agreement on visible mold being the standard is accepted by both the Occupational Health & Safety Administration ("OSHA") and the American Society for Testing and Materials ("ASTM"). OSHA makes no recommendations at all about sampling, deferring to EPA (*infra*), and ASTM states that no further sampling is

necessary or should be required once visible mold is present.[4]

As to consideration of temporal factors, ACGIH found "[t]he recognition of disease in one person may suggest that others who share the same work, residential, or recreational environment may also be at risk." ACGIH at § 8.5. ACGIH is not alone in such view.[5]

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[4]/ Indoor Air Quality in Commercial and Institutional Buildings, Occupational Safety and Health Administration, OSHA 3430-04 (2011). "This document . . . may be used as a basic reference for all those involved in IAQ issues." (OSHA at 3) Exhibit 3. The OSHA Guidance contains no recommendations for mold samples of any kind; instead the entire guidance focuses on proper building maintenance to prevent mold growths. As to what it is recommended when mold growths occur, OSHA says "[t]he most effective means to prevent or minimize adverse health effects is to determine the sources of persistent dampness in the workplace and eliminate them." OSHA at 15. OSHA Guidance issued in 2006 states that "[w]hen visible mold is present, cleanup can proceed on the basis of visual inspection. Sampling for molds and other bioaersols is not usually necessary." Preventing Mold-Related Problems in the Indoor Workplace, A Guide for Building Owners, Managers and Occupants, OSHA 3304-04N, 13 (2006).

Standard Guide for Readily Observable Mold and Conditions Conducive to Mold in Commercial Buildings: Baseline Survey Process, ASTM E2418-06 (March 2006). "As noted [by EPA], sampling cannot be used to access whether a building complies with federal standards, since no EPA or other federal standards or Threshold Limit Values (TLVs) have been established for mold spores. And, sampling would only produce results reflecting a specific moment in time in the best case and could produce inaccurate or misleading results in the worst case." Sec. 1.3.1, p. 1. Exhibit 4.

[5]/ The importance of temporal relationships in a damp indoor space building is well recognized. *See*, EPA at 39 (*infra* note 6) ("[w]hen moisture problems occur and mold growth results, building occupants may begin to report odors and a variety of health problems . . . all of these symptoms could potentially be associated with mold exposure.") (Adopted as a Virginia Professional Standard). "The recognition of disease in one person may suggest that others who share the same work, residential or recreational environment may also be at risk." ACGIH at § 8.5. Also a Virginia Professional Standard. "More recently, the relationship between [building related symptoms] and indoor mold exposure has been recognized . . .as a distinct symptom complex of mucous membrane, upper and possibly lower respiratory tract inflammation, fatigue and neurocognitive symptoms among occupants of mold contaminated buildings, with important features of temporality . . . consistency . . .and reversibility. The unique feature of 'building relatedness' distinguish these so called 'non-specific symptoms' from other common, non-building related disorders." IICRC at 42 (*infra* note 7) (also a Virginia Standard). *See also*, World Health Organization, *infra* note 20.

Given the above, Dr. Vance's opinions, based upon the observed and tested molds in the home, the potential for bioaersols (molds, VOCs and mycotoxins), the known moisture conditions and the relationship of all these factors to possible adverse health effects, are completely within the scope of his expertise and within the acceptable published guidelines and methodologies for his profession. It is not specific standards that are applied in his profession but the application of known effects of excessive moisture and mold growth conditions. This methodology is the professional standard, as indicated herein, is the proper methodology applied nationwide and is applied to the facts of this case. All conditions of *Daubert* are met by Dr. Vance.

After ACGIH released the bioaerosals manual, further mold guidance provided by the U.S. Environmental Protection Agency was published.[6] *See* Exhibit 5. The EPA found that "moisture control is the key to mold control" [EPA at 39], and "when excessive moisture accumulates in buildings or on building materials, mold growth will often occur, particularly if the moisture problem remains undisclosed or unaddressed [EPA at 2]. That is exactly what happened in this case. The EPA found "[w]hether dead or alive, mold is allergenic, and some molds may be toxic." EPA at 17. "All molds have the potential to cause health effects. Molds produce allergins, irritants, and in some cases, toxins that may cause reactions in humans." EPA at 40. As to mycotoxins, the EPA found that "molds can produce toxic substances called mycotoxins . . . Some of the molds that are known to produce mycotoxins are commonly found in moisture-damaged buildings." EPA at 41.

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[6]/ U.S. EPA, Mold Remediation in Schools and Commercial Buildings, EPA 402-K-01-001 (March 2001).

The EPA found that mold exposures can cause these same symptoms reported by the Plaintiff children in this case: allergic reactions, fevers, sneezing, runny nose, red eyes, skin rashes, irritation of the eyes, nose, throat and lungs, among others. EPA at 40,41. As noted, the EPA found that "visible mold" is the criteria for action and no further sampling is needed if visible mold is present. EPA at 25.

In 2003, the national Institute of Inspection, Cleaning and Restoration Certification (IICRC), a professional organization for water and mold damage remediation, produced its professional standards.[7] *See* Exhibit 6. The IICRC found:

> Molds develop from unique, microscopic seed-like structures called spores. Spores are not visible to the unaided eye. When spores settle on a surface under appropriate moisture and temperature conditions, they absorb water, swelling to 2-3 times their original size, and begin to form thread-like structures known as hyphae. As the hyphae grow, they interweave to form a tangled mass known as a mycelium. With continued growth, a mycelium, unlike a spore, becomes visible to the naked eye.

IICRC at 36.

It was further found that such mold growths produced odors (as here) (Vance T.29:9-14) and these odors are the product of mold VOCs.[8] IICRC at 39. Molds typically found in water

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[7]/ Institute of Inspection, Cleaning and Restoration Certification, IICRC S520 Standard and Reference Guide for Professional Mold Remediation (1st Ed. 2003) (since updated but changes do not affect cites herein).

[8]/ "In addition to visible mold growth and the detection of moisture in porous materials, an obvious indicator of microbial amplification is an odor that may be described as musty, moldy or mildewy. Fungi and bacteria produce a variety of volatile organic compounds (VOCs) during active growth. The microbial volatile organic compounds (MVOCs) we detect through our olfactory sense are generated by a variety of many molds and also by actinomycete bacteria, such as *Streptomyces* and related organisms." IICRC at 39.

damaged buildings also produce mycotoxins.[9] IICRC at 44. The IICRC Guidance also notes that it is not only the visible mold that is of concern, but that there may be "extensive mold growth" in concealed areas of water damaged buildings.[10] Regarding defense assertions of outdoor molds coming indoors, the IICRC found that an indoor building subject to water damage begins to grow molds known as water indicator fungi, which includes *Pencillium*, *Aspergillus*, *Stachybotrys* and others, all of which are associated with adverse health effects.[11] IICRC at 140. All these molds were found in the Plaintiffs' home. Vance T. 22:2-9.

The U.S. Dept. of Housing and Urban Development (HUD) released its mold guidance document in 2006.[12] *See* Exhibit 7. HUD found that "certain molds can cause a variety of adverse human health effects, including allergic reactions and immune responses (e.g. asthma), infectious disease . . . and toxic effects . . . ." HUD at 1. Citing other sources, HUD concluded that "it should be assumed that buildings or materials soaked for more than 48 hours are

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[9]/ "While much attention has been given to health concerns regarding *Stachybotrys chartarum*, certain species of *Aspergillus* and *Pencillium*, as well as *Fusarium*, and some other genera commonly observed colonizing water-damaged building materials, are also capable of producing a class of compounds known as mycotoxins . . .toxigenic mold." IICRC at 44. All these genera were present in the home.

[10]/ "There may be no visible mold growth on accessible surfaces or areas of the building and yet there may be extensive mold growth present in the interstitial spaces or concealed areas." IICRC at 67.

[11]/ "When the indoor (or built) environment is subjected to a moisture problem or a prolonged water intrusion, a group of molds begin to amplify that are referred to as water indicator fungi. They include species of *Pencillium*, *Aspergillus*, *Ulocladium*, *Stachybotrys*, *Fusarium* and others. These molds, depending on their nature, location and quantity, have been associated with adverse health effects in susceptible individuals." IICRC at 140.

[12]/ U.S. Dept. of Housing and Urban Development, Healthy Home Issues: Mold, Version 3 (March 2006).

contaminated with mold unless proven otherwise . . . ." HUD at 2.

Dr. Vance, in his report and throughout his deposition, stated that this was a water damaged building with water leaks from various sources (Vance T. 12:8-15; 13:4-15; 14:8-15), that excessive levels of mold were present (Vance T 11:13-25; 12:1-25; 13:1-25; 14:1-15; 20:16-22; 41:22-25; 42:1-2; 48:23-25; 49:1-25), that the molds indicated herein as water loving molds were found in the unit, and that the conditions in the unit were consistent with the production of odors (reported), VOCs and mycotoxins (Vance T 24:10-18; 29:2-25; 23:12-25; 24:1-18; 25: 8-25; 26:1-23; 29:5-25; 30:1-12; 47:8-25), all as reported in the literature relied upon by his profession, and that such conditions, in his professional opinion, constituted a potential health risk to the occupants. Vance T. 7:12-16. This is a traditional industrial hygiene opinion, applying professional methodologies in his field and the facts thereto.

This Court is advised that although no national standards exist for mold exposures, all of the above cited materials provide the professional consensus position for the testimony of an industrial hygienist on mold, moisture and water-damaged building conditions, and the expected mold and microbial products found therein. There is no opposing industrial hygienist as a witness. Most important of all, however, is the fact that the Commonwealth of Virginia has adopted the professional documents cited above as the "professional standards for mold remediation." Va. Code § 8.01-226.12.[13] These standards are embodied in statute and are

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[13]/ "Mold remediation in accordance with professional standards" means mold remediation
of that portion of the dwelling unit or premises affected by mold, or any personal property of the tenant affected by mold, performed consistent with guidance documents published by the United States Environmental Protection Agency, the United States Department of Housing and Urban Development, the American Conference of Governmental Industrial Hygienists (the Bioaerosols Manual), Standard Reference Guides of the Institute of Inspection, Cleaning and Restoration for

mandatory in application. Therefore, while no national standards exist, there are Virginia standards by statute, entitled to judicial notice and application by this Court, and expert Dr. Vance has referenced, followed and applied such standards in his opinions. This alone removes any possibility of a *Daubert* issue.

Finally, Defendants assert that Dr. Vance will offer a medical causation opinion. Def. Mem. in Support at 7. The basis for this position is that any person who discusses "general health effects of molds" is "synonymous" with a medical causation opinion. This is incorrect. Dr. Vance reviews the facts, applies the professional guidelines and methodologies and then opines whether such facts and literature indicates that a general adverse health effect could result from such exposures. That is not a causation opinion, and is well within his area of expertise. Dr. Vance has made it clear that he was not rendering any medical causation opinions. Vance T.7:15-16; 33:6-20.

Dr. Vance meets all possible *Daubert* conditions and the motion to exclude him on such grounds is without merit and borders on the frivolous.

DR. VILSECK'S METHODS, REFERENCES AND DIAGNOSES FOLLOW ACCEPTED MEDICAL PRACTICE CONSISTS EXPOSURE EVALUATION AND

To avoid unnecessary repetition, the literature cited for Dr. Vance is also incorporated for Dr. Vilseck. Defendants seek exclusion of Dr. Vilseck on the grounds of (1) improper and unreliable methodology; (2) science not accepted in the medical community; and (3) failure to consider all sources of exposure as part of the diagnosis. None of these arguments have any

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Water Damage Restoration and Professional Mold Remediation, or any protocol for mold remediation prepared by an industrial hygienist consistent with said guidance documents." Va. Code § 8.01-226.12

merit or support, and represent, at best, no more than conflicting opinions of opposing experts.

Dr. Vilseck performed his four factor causation analysis in accordance with established clinical guidance and national literature concerning mold causation. The first factor to be consideration is allergic response. Vilseck 12:5-25; 13:1-25; 14:1-3 (was there an allergic reaction?). The second factor to be considered was the contemporary illness among all family members in the same building. Vilseck T. 14:4-19 (an important factor in damp indoor analysis, see below). The third factor considered was the type of molds in the subject unit. Vilseck T. 14:20-25; 15:1-16 (mold potential to cause illness, VOCs and irritation, all present); The fourth factor considered was exposure. Vilseck T. 15:17-25; 16: 1-17 (long term exposure, one year nine months was "exceedingly long").

Before further describing the specifics of Dr. Vilseck's opinion, Plaintiffs will address the national medical consensus on mold exposures and adverse health effects, as Dr. Vilseck relies on this consensus in addition to his 40 years of experience in allergy and pulmonary medicine.

As already shown by previous references for Dr. Vance, it was well known and understood as early as 2001-2003 in the industrial hygiene community, by EPA and HUD, that mold exposures can cause adverse human health effects. Defendants' own experts admit this is still the issue today, they just disagree with Plaintiffs' experts in this case:

> "While the body of scientific evidence may support allergic symptoms in someone with allergies to specific mold species, a careful causation analysis in this matter find no evidence [of causation].

Dr. Cheung, Expert Rept. at 17. Exhibit 8.

> "Molds may cause a wide spectrum of illnesses, including allergies, irritation, hypersensitivity pneumonitis, and direct infection. However . . . contentions of the Plaintiffs are inconsistent with opinions accepted by the general medical

community."

Dr. Phillips, Expert Rept. at 17. Exhibit 9.

As to the first factor, both Defendants' experts recognize that molds can cause allergies. This is the same opinions shared by EPA and Institute of Medicine (*infra*).

The second factor, temporal or "contemporaneous" relationship, has been throughly evaluated with respect to damp indoor space exposures. As Dr. Vilseck found "the whole family at one time was ill, with the signs and symptoms that are strongly associated with the mold growth and especially the volatile organic compounds." Vilseck T. 39:13-16. The clear consensus opinions are that a temporal relationship between the unique conditions in a damp indoor space and microbial exposures produces a distinct symptom complex among occupants of mold contaminated buildings. EPA, ACGIH, IICRC and the WHO agree. *See* Note 5, *supra; see also Westberry* at 265.

What really remains of Defendants' argument is the medical and scientific information on specific causation, and whether Dr. Vilseck presented an adequate assessment of the childrens' health to meet *Daubert* requirements to present his opinions to the jury.

Expert opinions on causation are often in the eye of the beholder, and nothing could be more true, unfortunately, in expert opinions on personal injury of all kinds. The fact is that a water damaged building, almost universally referred to as a "damp indoor space," contains a mixture of molds, microbial products, VOCs and bacteria that can cause human illness. As discussed below, there is no dispute that molds are allergens, that they cause allergic reactions, and that exposure to molds can sensitize persons to become mold allergic and to acquire other allergies as well. There is no dispute that mold exposures can cause respiratory problems and

other traditional upper respiratory problems (eye, nose and throat), all as suffered by the Plaintiff children in this case. Thus, an allergy and pulmonary specialist, such as Dr. Vilseck, who has seen thousands of allergy and pulmonary patients in his clinical practice (Vilseck T. 113-114) is fully capable of applying the established medical and scientific literature, the facts at hand, and his clinical expertise to render an opinion consistent with *Daubert* criteria.

First, a review of the governmental and national treatises on mold. After mold exposures became a national health concern in the late 20th Century, the National Academy of Sciences tasked the prestigious Institute of Medicine (IOM) to prepare a treatise on mold health effects.[14] See Exhibit 10. Published in 2004, the IOM could only consider literature developed through 2002, just after the 2001 EPA guidelines were issued. Nonetheless, the IOM found water damaged buildings, which it referred to as "damp indoor spaces" to be a significant health issue. "Damp indoor environments favor house mites and microbial growth, standing water supports cockroach and rodent infestations, and excessive moisture may initiate chemical emissions [VOCs] from building materials and furnishings." IOM at 1. Condensing 355 pages of detailed research and reporting of epidemiological studies, the IOM found "sufficient evidence of an association between exposure to a damp indoor environment and upper respiratory tract symptoms," i.e., the bronchitis and sinus symptoms of the children. IOM at 194. "Sufficient evidence of association of the presence of mold in a damp indoor environment and upper respiratory tract symptoms." *Id.* The same sufficient evidence was found for cough, wheeze, asthma symptoms, and certain types of pneumonia for exposures to mold and damp indoor conditions. IOM at 201, 208, 226, 233.

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[14]/ Institute of Medicine, Damp Indoor Spaces and Health, 2004.

The IOM identified "mycotoxins" as present and problematic in damp indoor spaces, and reported that the mold "smell" in damp indoor spaces, as opined by Dr. Vance, was directly caused by the microbial VOCs which are "toxic or otherwise biologically active."[15] This information was important to Dr. Vilseck as well, who also opined, consistent with the IOM , that such odors reported by the childrens' parents indicated the presence of mycotoxins and VOCs and was a "rule-in" factor for mold causation. Vilseck T. 15:1-5; 95:14-25; 96:1-16. The IOM reported that exposure to microorganisms and their products can irritate mucous membranes and lead to inflammatory immune responses. IOM at 133. These inflammatory responses, if chronic or excessive, can lead to lung damage, a critical factor in this case (see below).

Defendants point the Court to the fact that the IOM stopped short of specific causation for mold health effects, instead showing an epidemiological association. However, treating doctors and experts routinely rely upon epidemiological associations, tested against the facts at hand and excluding other reasonable causes, to form a causation opinion admissible under *Daubert*.

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[15]/ "MVOCs [microbial volatile organic compounds] are small-molecule, volatile substances that are typically released by growing fungi and bacteria as end products of their metabolism. They are often odorous, causing the typical smell of 'mold,' 'cellar,' or organic soil. . . . Many secondary metabolites are toxic or otherwise biologically active. Commonly known microbial secondary metabolites are mycotoxins, bacterial toxins, antibiotics, and antimicrobial agents." IOM at 69. The effects of such mycotoxins can be significant. "Mycotoxins are found in and on materials that can be aerosolized . . .some are semivolatile, and others are at least partially water soluble . . . The toxic effect of spores and other particles on alveolar macrophages can impair the ability . . . to protect against . . mycotoxins . . .other bacteria and infectious particles." IOM at 128, 130. "Some of the studies . . .indicate that acute inhalation exposure, at least some of the toxicants, is at least as toxic as by intravenous injection and is more toxic than ingestion or parental exposure." IOM at 131.

At about the same time the IOM report was being completed, the University of Connecticut Health Center ("UCHC"), in concert with an EPA grant, published a guide for clinical assessment and management of mold and moisture indoor exposures.[16] *See* Exhibit 11. This document remains today the comprehensive clinician's guide to mold exposure assessment by the medical community. "Mold," for the purposes of the UCHC, like EPA and others, simply refers to "a visible colony of fungi growing in an indoor environment." UCHC at 16. The UCHC guide advises clinicians that bacteria are also likely present in a water damaged building, which is directly relevant to the chronic bronchitis and pulmonary problems suffered by the Plaintiff children in this case.[17] The UCHC Guide states that fungi can cause disease in humans by a variety of means, including infections, allergic responses, irritant reactions and toxic reactions, affirming all previous literature reaching the same conclusions. UCHC at 21. The same reactions Dr. Vilseck rules in for this case, which in addition to lung damage, includes the extensive allergic reactions of the children.

With respect to allergy sensitization, an important component of mold illness and Dr. Vilseck's opinion, the UCHC Guide finds that individual immune responses are determined by genetic makeup and environmental factors, and important to these reactions are the frequency of exposure and the intensity of such exposures. Once sensitization has developed, however, it

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[16]/ Storey, Eileen, et al., Guidance for Clinicians on the Recognition and Management of Health Effects Related to Mold Exposure and Moisture Indoors, Univ. of Connecticut Health Center, Division of Occupational and Environmental Medicine, Center for Indoor Environments and Health, September 20, 2004.

[17]/ "It is important to note that bacteria also grow on building materials and are likely contributors with fungi of bioaersols to the indoor environment. In a water-damaged environment, environmental bacteria such as gram-negatives and actinomycetes may amplify with molds." UCHC at 16.

requires a much lower re-exposure to elicit the same or greater response; in fact, repeated exposures usually result in progressive worse allergy symptoms, exactly as Dr. Vilseck has found.[18] Further, the UCHC Guide notes that "a single fungal genus (e.g. *Pencillium*) may produce more than 100 different mycotoxins." UCHC at 27-28. This fact supports the presence of mycotoxins in the subject unit, where *Pencillium* genera molds were found; differentiation by species, as argued by Defendants, is not required, and Defendants produced no literature citation to support such claim.

Sensitization was a major factor for Dr. Vilseck. First, Dr. Vilseck confirmed that sensitization is a major component of mold, VOC and mycotoxin exposures, exacerbating existing allergies and causing responses to new allergens, and second, he applyied same to the symptoms and facts of this case. Vilseck T. 40:15-25 (sensitization occurs); 41:1-20 (citing literature); 42:1-25 (sensitized here); 43:1-25 (made worse); 66:1-4 (sensitization cause of current allergic responses); 66:5-25; 67: 1-12 (sensitization reactions in K.K.); 73:4-20 ("without reservation" caused non-sensitive person to become sensitized). This is consistent with the above findings of the EPA, IOM and UCHC.

In directing doctors in a clinical assessment, the UCHC Clinicians' Guide states mold identified in air samples inside, normally, should be less than outside air (because the indoors is protected); when mold concentrations inside are higher relative to outside levels (as here), indoor

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[18]/ "Individuals' immune responses to these antigenic molecules [aerosols] are determined by their genetic makeup and environmental factors. Important among these factors are the frequency of exposure to the antigens and the intensity of the exposures. . .Once sensitization to an antigen has developed, it requires a much lower concentration upon re-exposure to elicit the reactive phase that we recognize as the clinical manifestation of the disease." UCHC at 23. "One distinguishing feature is that with repeated exposures, allergic symptoms become increasingly worse because of increase sensitization." UCHC at 27.

"mold growth" is indicated. UCHC at 55. Elevated growths of indoor mold were found in the subject unit and Dr. Vance opined that this fact indicated that mold was growing *inside* the home. Vance T. 20:18-19; 43:16-25; 44:1-8; 49:18-25; 50:1-2. Dr. Vilseck described the mold growth occurring inside the home as "impressive." Vilseck T.109:1-9. Remarking about the established fact that indoor mold growths should not exceed outdoor growths, and finding that *Aspergillus*, *Pencillium* and *Stachybotrys* molds are higher proportionally indoors when compared to the outside, Dr. Vilseck opines that this "case is about indoor exposure not outdoor exposure." Vilseck T. 111:2-3. Both children are allergic to *Aspergillus* and *Pencillium* (K.K., Vilseck T. 79:23-25; 80:1-3 [big reaction]; Alex, Vilseck T. 57:18-22 [good, pertinent reactions]); *Stachybotrys* can not tested by skin tests because of its toxicity.

In addition to the *Pencillium*, the UCHC Guide also reports that species of *Aspergillus*, also found in the subject home, "are notorious for producing mycotoxins" and further present a "serious" health concern because of their infection potential. UCHC at A-1. *Aspergillus* was found inside the unit at higher than outside concentrations. Vance T. 22:8-9; 31:21-24;49:1-17. Dr. Vance, consistent with the UCHC Guide, opined that mycotoxins and VOCs were being produced by the molds growing in the home. *See*, Vance *supra.* Dr. Vilseck's opinions were consistent.

Both IOM and UCHC strongly support Dr. Vilseck's causation analysis. Both point to damp indoor spaces as growing mold, the importance of duration and exposure in damp indoor spaces, that molds produce VOCs and mycotoxins, and that molds have the potential to cause human illness.

Following the flooding by Hurricane Katrina, the U.S. Centers for Disease Control and

Prevention ("CDC") issued its report on mold.[19] See Exhibit 12. The CDC confirmed that "substantial indoor mold growth is virtually synonymous with the presence of moisture inside the building envelope." CDC at 4. The CDC affirmed the IOM findings, expanding to include more ways that mold can cause human health effects, pinpointing inhalation of aerosolized spores and fragments from large masses of mold "such as might occur in a building." CDC at 4. The CDC found that because no standardized methods exist, individual susceptibility and the interaction of molds with other microorganisms and chemicals, it is not possible to sample an environment, measure the mold level in that sample, and make a determination on whether the level is high or low with respect to adverse human health effects. CDC at 4 (Exactly as Dr. Vance stated and was criticized for, Def. Mem. In Support at 6). Dr. Vilseck, as with the CDC, does not compare these exposures to standards, because there are none, but instead looks to whether symptoms and exposures are consistent and whether duration of exposures to molds capable of causing human illness was present. The CDC outlined a long list of human health effects that mold and damp indoor space environments can cause, including as here, allergic, infectious and respiratory conditions. CDC at 16, 17.

Concluding, the CDC stated "mold and its spores exist in damp materials. Disturbing mold releases potentially hazardous particulates into the air, which can then be drawn into the sinuses and lungs. Although molds also might directly attack the skin or openings in the skin, the most common route of exposure is through the air and into the body by inhalation." CDC at 24. Vilseck T. 16:18-25 (inhalation primary route). Thus, the CDC describes both the

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[19]/ Centers for Disease Control and Prevention, Mold Prevention, Strategies and Possible Health Effects in the Aftermath of Hurricanes and Major Floods, CDC MMWR Recommendations and Reports, 55 (RR08), 1-27 (June 9, 2006).

mechanism for mold exposure and the route of human infection, exactly as found in the subject home, and stated by Dr. Vilseck. The CDC, like all other governmental and scientific treatises, makes little or no mention of any "dose" relationship for damp indoor space exposures, which is consistent with Dr. Vilseck's analysis. Vilseck T. 22:4-9 (never sees literature using dose response for moisture and mold exposures). Dr. Vilseck's opinions are consistent in that he finds that excessive moisture and leaks are the problem in this home and would grow molds known to cause adverse health effects. Vilseck T. 15:17-25 (long term water problem) and Vilseck T. 15:1-5; 14:4-19 (molds present).

In 2009, responding to the growing mold and damp indoor space problems world wide, the World Health Organization (WHO) issued their report on indoor quality in 2009.[20] See Exhibit 13. Applying more recent medical and scientific literature developed after 2004, the WHO found that "[m]icrobial pollution is a key element of indoor air pollution" and is "caused by hundreds of species of bacteria and fungi, in particular filamentous fungi (mould), growing indoors when sufficient moisture is available." WHO Abstract. The WHO found that building moisture produces all the molds, VOCs and bacteria alleged in this case, and excess moisture (not humidity) is usually the result of a building fault, such as the roof and skylight leaks noted by Dr. Vance, and by Dr. Vilseck in his diagnosis.[21] The WHO confirmed that no health

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[20]/ World Health Organization, Guidelines for Indoor Air Quality: dampness and mould (2009).

[21]/ "The presence of many biological agents in the indoor environment is due to dampness and inadequate ventilation. Excess moisture on almost all indoor materials leads to the growth of microbes, such as mould, fungi and bacteria, which subsequently emit spores, cell fragments and volatile organic compounds into indoor air." WHO at XII. "The amount of water on or in materials is the most important trigger of the growth of microorganisms, including fungi, actinomycetes and other bacteria . . .Microbes propagate rapidly whenever water is available."

standards are possible for such multiple exposures, leaving treating doctors and medical experts to make such connections based on the evidence of moisture and mold presence combined with known symptoms.[22]

Although the WHO organization also stops short of specific causation, it states that the development of medical research has brought the world to the verge of causation findings for house dampness, mold exposures and adverse human health impacts:

> The overall evidence shows that house dampness is consistently associated with a wide range of respiratory health effects, most notably asthma, wheeze, cough, respiratory infections and upper respiratory tract symptoms. These associations have been observed in many studies conducted in many geographic regions . . . Positive associations have been found in infants, child, and adults . . .For one

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WHO at XIV. "Microbial growth may result in greater number of spores, cell fragments, allergens, mycotoxins, endotoxins, B-glucans and volatile organic compounds in indoor air." WHO at XIV. "In most climates (e.g., Europe), adequate ventilation, heating with adequate moisture control and thermal insulation of building structures will be enough to keep relative humidity on and in building structures within acceptable limits. Thus, microbial growth and dampness are usually indicators of construction faults, moisture damage, or malfunction of ventilation or heating systems." WHO at 55-56.

[22]/ "As the relations between dampness, microbial exposure and health effects cannot be quantified precisely, no quantitative health-based guideline values or thresholds can be recommended for acceptable levels of contamination with microorganisms. Instead, it is recommended that dampness and mould related problems be prevented." WHO at XV. "In damp buildings, people are exposed to constantly changing concentrations of different microbial species, their spores, metabolites and components, and other compounds in indoor air, including chemical emissions from building materials. This complex mixture of exposures inevitably leads to interactions, which may change the toxic characteristics of the inhaled particles, causing different outcomes in different situations." WHO at 85.

WHO found that the exposures could not be characterized by dose levels derived from animal exposures: "the effects of microorganisms, microbial substances or dampness-related chemical compounds seen in experimental animals or cells often result from exposures that are orders of magnitude higher than the average doses that reach human lungs under normal conditions of indoor air. Nevertheless, the surface doses within the lungs of patients with respiratory conditions can vary a thousandfold, due to uneven particle deposition, resulting in even larger maximal surface doses in human lungs than those used in experimental toxicological studies." WHO at 85.

> health outcome, asthma exacerbation, we consider the evidence to be sufficient to document an association and almost sufficient to document causality of dampness related factors . . .In all the available studies, dampness-related factors were consistently exceeding 1.0. This was true for both adults . . .and in all cross-sectional studies . . .and children.

WHO at 70-71.

It is beyond the space of this brief to cite every relevant finding reported in the large WHO treatise. WHO does confirm mycotoxins as very toxic, often at very low concentrations. WHO at 81. Of particular note is the WHO conclusion that "inhalation fever, also known as toxic pneumonitis, . . .occurs after inhalation of a wide range of substances, from metal fumes to bacteria and mould spores." WHO at 83.

On this important point, Dr. Vilseck first recognizes that inhalation is the primary source of aerosol exposure, i.e., what you breathe into your lungs. Vilseck T. 16:18-25. Second, reviewing the symptoms in this case reported independently by other doctors (Dr. Frye, Dr. Dearborn at the Cincinnati Childrens Hospital, and various hospitals and emergency rooms, Dr. Vilseck found that the health records at the time of exposure showed that both children had a significant frequency of high fevers, particularly so for A.K. Vilseck T. 29:6-24 (a fact overlooked by many doctors, including the defense experts). Both by history and other doctors, including independent examinations by Dr. Frye, Blumberg and Dearborn, Dr. Vilseck ruled out bacterial and viral infections as the principal cause of these fevers. Vilseck T. 29:10-13 (searched for same); Vilseck T. 70:1-3 (no proof of viral or bacterial infections, i.e., no nasal smears); Vilseck T. 70:9-25 (neither treatment with antibiotics or passage of time resulted in improvement); Vilseck T.71:1-6 (but conditions in home would explain and are consistent). Dr. Vilseck's concerns about the failure of the children to respond to traditional antibiotic therapy

was also voiced by Dr. Frye (below).

Dr. Vilseck reviewed independent x-rays taken of both children in Cincinnati as the children complained of these repeated fevers. Dr. Vilseck, as did other independent treating doctors Blumberg and Dearborn, found the x-rays to show that *both* children had lung inflammation and defined lung damage, described as peribronchial thickening. Vilseck T. 30:15-21. In his deposition, Dr. Vilseck linked all these factors together, including references to established literature to render a diagnosis of inhalation fever caused by mold exposure. As Dr. Vilseck stated in his deposition:

> This young man had periodic fevers . . . T.29:16-17; in the literature, the World Health Organization, there's such a thing called inhalation fever (see above). That has been termed toxic pneumonitis. It occurs in a wide range of substances, such as bacteria and mold spores, T. 30:10-14; This young man not only had periodic fever, but, if you look at his chest x-rays . . . he had peribronchial thickening and so did his sister, T. 30:18-21; no one really delved into mold problems like we do . . .I'm a medical microbiologist . . .I [look] at things differently. I never saw mold like this except for brown lung. T. 32:18-23. Peribronchial thickening . . . that's critical in this case . . . It does occur after inhalation of a wide range of substances, of which bacteria and mold spores are. T. 32:1-9.

The WHO document also reports that infections with *Aspergillus* and other fungi is a well known complication in treatment of immune compromised, or atopic (as was A.K.) persons; and that *Aspergillus* is particularly aggressive in this regard and results in "exaggerated" responses to other common molds, particularly *Alternaria*.[23] This situation matches this case precisely: investigators found higher levels of *Aspergillus* inside the unit, the children had repeated

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[23]/ "Infection with *Aspergillus* and other fungi such as *Fusarium spp*. is a well known complication in the treatment of patients who are immune compromised . . . *Aspergillus* appears to be the most aggressive of these fungi . . . People with atopy sometimes develop sinus disease as a consequence of *Aspergillus* infection or presence. Exposure to mould has been proposed as the cause of chronic sinusitis, as these patients show exaggerated humoral and cellular responses both T(H)2 types, to common airborne fungi, particularly *Alternaria*." WHO at 83-84.

infections which Dr. Frye said were not responding to normal antibiotic therapy (see Frye below), and the children had early allergic reactions to *Alternaria*. Plaintiffs' doctors can match the medical facts, including symptoms, with the investigation, and all fit. When Dr. Vilseck tested the children for allergies in 2011, both were highly allergic to all molds as well as many other allergins; i.e., they were completely sensitized. Vilseck T. 402-25; 41-1-25; 42:1-12. There is no evidence of any other source of allergenic exposures for these children other than that common to everyone, i.e., there were no occupational exposures (these are young children), they didn't live next to industrial complexs (lived in a rural residential home), no smokers in the home, the subject home was decades old and had no exceptional internal sources of VOCs except for molds, and other treating doctors (Blumberg) excluded other factors such as food allergies (Vilseck T. 58:18-25; 59:1-6) and reported no alternative causation findings that were inconsistent with mold exposure. Dust mites were present, but indoor moisture produces dust mites so the damp indoor space conditions would have produced mites. See, WHO infra. Nevertheless, skin testing for mites right after exposure (January 2003) "didn't show mite, not much." Vilseck T. 46:13.

Finally, the WHO found a positive association between the musty or moldy odors found in damp indoor spaces with human illness, again affirming this simple observation as diagnostic of mold and mold product exposures.[24] WHO at 87.

Dr. Vilseck conclusively concludes that the children have "hyper-reactive airway disease"

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[24]/ "Spores and other particulate material, as well as volatile organic compounds produced by microorganisms, building materials, paints and solvents, are potentially irritating. In epidemiological studies, the prevalence of respiratory and irritative symptoms has been associated with perceived mould odour, possible [sic] indicating the presence of microbial organic compounds." WHO at 87.

caused by exposures in the home (Vilseck T. 44:11-25; 45:1; 55:3-25; 56:1-6), the allergic reactions suffered by K.K. were caused by mold and bioaersol exposure in the home, and the allergies of A.K. were exacerbated. Vilseck T. 48:24-25; 49:1-25; 50:-1-25; 51:1-25; 61:8-19; 64:12-14. Dr. Vilseck has ample governmental, scientific and medical documents, as cited above, to affirm a general causation in this case, to the extent that is even an issue, and applies methodologies published by EPA, uses national clinical guidance, and treatises such as the IOM , CDC and WHO to inform him of the associations and relationships known in the medical world. Applying this information to the facts of this case, which are consistent in every way with such literature, and using his 40 years experience as a clinical doctor, finding no substantive confounding factors, and finding specific lung and allergic injury also documented by other independent testing and the contemporaneous treatment by Dr. Frye, Dr. Blumberg, Cincinnati Childrens' Hospital, and various hospitals and emergency rooms Dr. Vilseck meets every tenet of *Daubert* to provide a specific causation opinion. Contrary to Defense experts and briefs, the *Daubert* test is not uniform medical consensus. Medical consensus was an element of the old *Frye* expert test, which the U.S. Supreme Court rejected with the adoption of *Daubert* criteria. This Circuit rejects any application of an "uncompromising general acceptance" rule. *Cavallo v. Star Enterprise,* 100 F.3d at 1158-1159 (citing *Daubert* at 595-97). Defense experts may disagree with Dr. Vilseck, but the overwhelming national and international medical and scientific literature generally accepted in this area is not with the defendants, and, therefore, this is not a *Daubert* issue.

DR. LIPSEY MEETS DAUBERT CRITERIA TO RENDER TOXICOLOGY OPINIONS

Defendants assert that Dr. Lipsey must be excluded, or at least limited in his opinions

because (1) he renders medical causation opinions and is not a doctor; (2) opinions on the presence of mycotoxins is unsupported; (3) opinions of the presence of VOCs in the home is unsupported; and (4) his opinion of the presence of high levels of *Stachybotrys* molds is unsupported. Like Dr. Vance, Dr. Lipsey's opinions are well within the mainstream of reported literature and professional methodologies regarding damp indoor spaces. Again, to save repetition, Plaintiffs incorporate the materials already referenced herein.

Dr. Lipsey is a senior toxicologist, who has been involved in fungal toxicology for 40 years, having done his PhD thesis on fungal toxicology. He teaches toxicology, and has served in such capacity in both the private and governmental functions for years. Lipsey T. 5,6, 7:1-16.

First, Dr. Lipsey does not render any medical causation opinion, and he stated so on several occasions at his deposition. Lipsey T. 14:25 ("I do not give medical causation"); 17:6-7 ("I don't give medical causation"). It is the function of a toxicologist to explain the mechanism by which a toxic element can cause harm, and the nature of the harm that can be caused. Lipsey T. 16:11-24 ("I depend on this stack of literature, these scientific articles that I've brought and there are hundreds of them, that clearly say mold can cause the symptoms this family had."). Toxicologists follow certain methodologies in their fields, render opinions about what can happen and why, and the potential health risk presented. Making these statements is not converted to a specific causation opinion by the mere fact that the toxicologist makes such conclusions. *See*, *Tunnell v. Ford Motor Co*., 330 F.Supp. 2d 731, 735 (W.D. 2004). What is relevant for this motion is whether Dr. Lipsey "employed recognized methodologies based on the facts of the case." *Id.*

As a general matter on methodology, Dr. Lipsey states that he relies on two well known

causation assessment research methods, the Koch postulate criteria and the Bradford Hill Criteria, which he has applied in courts nationwide for years. Lipsey T. 10:16-19; 16:13-24; 17:5-13 (outlining basic criteria of exposure to molds in home, symptoms consistent, strong temporal and spatial relation, other causes excluded, and defined illness compared to literature); *see also* Lipsey T. 9:7-25; 10:1; 66:21-25; 67:1-25; 68:1-12 (more detail on basis for exposure, symptoms, temporal relationship and consistency with literature).

Basically, the remainder of Defendants' motion is based on the fact that no samples were taken for VOCs or mycotoxins, and without such sample data to presumably compare to some standard, Dr. Lipsey's testimony is inadmissible even if all methodologies were followed. It has already been demonstrated that sampling for mold VOCs and mycotoxins is not recommended. As noted, such sampling is not likely to be accurate of exposure, and at worse could be misleading. Thus, the methodology, in the investigation of damp indoor spaces, by Virginia Professional Standards, EPA, OSHA, ASTM and UCHC is to not sample because it is now understood that the components of a "damp indoor space" are moisture, mold and the mold byproducts VOCs and mycotoxins. Dr. Lipsey can, and does go further in opining that VOCs and mycotoxins are present because he knows, from sampling done, that the particular mold *Stachybotrys* was present in the home in "heavy quantities." Lipsey T. 9:11-21; 10:25; 11:1-4 (leaks had to highly significant . . . for *Stachybotrys* to grow to heavy concentrations); 24:11-25 (heavy *Stachybotrys* produces trichothecenes in heavy doses); 28:22-25; 29:1-25; 30:1-6 (in 38 years of testing homes, always found mycotoxins present if sampled, when *Stachybotrys* present); 34:5-22 (not just his opinion about toxic mold and mycotoxins, but literature as well [see herein]); 56:1-9 (in his experience "heavy" means millions of spores).

The presence of "heavy" concentrations of *Stachybotrys* in the home was confirmed by independent mold sampling in the home at the time of exposure; like any expert, Dr. Lipsey may rely upon such testing results, which are not challenged by Defendants and were reported by the laboratory according to their standards and protocols. Plaintiffs have identified the laboratory representatives to testify about these test results and Defendants have not objected to such expert witness. As to the presence of mycotoxins, Dr. Lipsey relies on the overwhelming scientific and medical literature that *Stachybotrys* molds produce mycotoxins, and that these compounds are present in water damaged buildings with *Stachybotrys* growths.[25] As Defendants note, Dr. Lipsey is not testifying that any mycotoxin, by itself, could have caused the injuries complained of by the children. He proposes to testify that these mycotoxins are part of the mixture of molds and mold byproducts in the home and can contribute to the toxic impacts on the children. Defendants are attempting to exclude testimony which is descriptive of the toxic conditions in a water damaged home, which is inappropriate.

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[25]/ "Molds can produce toxic substances called mycotoxins . . . Some of the molds that are known to produce mycotoxins are commonly found in moisture-damaged buildings." EPA at 41. "[I]t is clearly prudent to avoid exposure to molds and mycotoxins." EPA at 42. "[C]onfimed presence of *Stachybotrys chartarum* . . .requires that urgent risk management decisions be made." ACGIH at 19.5.1.3, citing American Industrial Hygiene Association. "*Stachybotrys chartarum* . . .can also produce potent mycotoxins and has been associated with serious health effects." IICRC at 5. These citations, EPA, ACGIH and IICRC are professional standards adopted by Virginia, which Dr. Lipsey is bound to follow.

There is no question that *Stachybotrys* contamination in a water damaged home can cause injury through mycotoxin production. "Trichothecenes [a mycotoxin] from *Stachybotrys chartarum* were isolated from contaminated insulation and ductwork in a house. Workmen handling the material without skin protection suffered painful skin lesions on their hands, armpits and genitals." IOM at 166. "*Stachybotrys chartarum* trichothecene mycotoxins can become airbornes in association with both intact conidia and smaller fungal fragments . . . These studies demonstrate that mycotoxins are present in the indoor environment and that the levels may be higher in buildings affected by mold or damp." WHO at 19.

Defendants' brief repeatedly confuses argument about mycotoxins, *Stachybotrys* and VOCs making it difficult to respond, but it appears that Defendants challenge any statements about the presence of VOCs in the unit on the same grounds as mycotoxins, i.e., they weren't measured so the expert cannot render an opinion about them. Like mycotoxins, Dr. Lipsey opines that VOCs were present and contribute to the mix of harmful exposures for the children. VOCs are irritants and can cause some of the respiratory problems observed in the children, and like mycotoxins, VOCs are recognized as present in water damaged buildings with mold growth. *Supra.* Lipsey T. 9:7-21 (VOCs produced by molds); 24:1-2 (VOCs have similar symptoms as mold spores); 24:24-25; 25:1-11 (molds digest organic matter . . .producing VOCs . . .can be trimethylbenzenes, benzene, tilolene [sic]. . .all can cause respiratory effects); 54:12-19 (molds produce VOCs when they digest damp organic matter); 54:24-25; 55:1-25 (VOCs in home to a high degree of certainty); 58:1-21 (no occupational limit for VOCs, even if existed, that would apply to two year old girls); 59:1:9 (since benzene, among other known carcinogens, is a VOC produced from molds, there is no safe level for such VOCs under NIOSH, again sampling is irrelevant); 61:5-11 (other VOC exposures, i.e., cleaners, in this home played no major role with heavy *Stachybotrys* present); 61:16-21 (normal symptoms of VOC exposure are headaches and upper respiratory problems [as here]).

As already shown, mold investigators may use observational data to assume the presence of VOCs and mycotoxins, without any further sampling. ACGIH at § 14.2.1 (professional standards in Virginia). The EPA (also a Virginia Professional Standard), holds that microbial VOCs are produced by molds and have unpleasant odors. EPA at 43. The mere presence of these moldy odors, as already identified and found in the home, confirms the presence of mold

VOCs.[26] Thus, this information is sufficiently supported and relevant because (1) it is further confirmation of excessive mold growths; and (2) confirms another component of the mixture of contaminates these children faced.

Dr. Lipsey's proposed testimony is consistent with the Virginia Professional Standards, the positions of the EPA, ACGIH and IICRC, as well as the IOM and WHO. Informing the jury of the types of compounds known to be present inside a damp indoor space and how such compounds can increase the health risk, is the purpose of toxicological opinions. Measuring the specific amounts of these compounds in any given building and then comparing them to occupational standards, if any, has already been shown by the above entities to be not only impractical and unnecessary, but of no real use is assessing the impact of such mixtures and individual exposures, and Virginia Standards do not require it to assess a water damaged building.

Since the Defendants did not address any other opinions by Dr. Lipsey, such as mold symptoms, mold adverse health effects or other testing in the home, Plaintiffs will not reargue the deposition testimony or his report as these issues are unopposed.

DOCTOR FRYE MAY TESTIFY AS A TREATING DOCTOR

Dr. Frye was the treating doctor for the children during and immediately after their exposures in the subject home. She examined and treated K.K. within two months of birth, and continued to treat K.K. through April 15, 2002, and treated and examined A.K. from July 18,

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[26]/ "Some compounds produced by mold are volatile and are released directly into the air . . . Because these compounds often have strong or unpleasant odors, they can be the source of odors associated with molds. Exposure to microbial VOCs from molds has been linked to symptoms such as headaches, nasal irritation, dizziness, fatigue and nausea." EPA at 43.

2001 through January 16, 2002, all within the critical period of occupation of the subject home, which was from August 2000 to April, 2002. Frye T. 12:18-22; 13:1-16. Dr. Frye rendered her final medical diagnosis of the children in a May 6, 2002 letter. Exhibit 14. Dr. Frye began treatment for identifiable "mold" symptoms in December 2001 for K.K., and October 22, 2001 for A.K. Frye T. 14:19-22; 15:1-6.

Dr. Frye is a "treating doctor" under the case law of this Circuit; she was not retained by counsel, rather she independently treated the children and independently diagnosed them as suffering from mold exposures. Dr. Frye applied traditional methods of diagnosis, which included identification of symptoms consistent with mold exposures, Frye T. 15:4-13, and researched these symptoms and conditions for consistency with published medical treatises (read Harrison's Internal Medicine and infectious disease references). Frye T. 15:17-22; 16:1-18; 28:19-22; 29:1-4 (would never write such a letter without backing it up with medical support). Contrary to the argument of Defendants, Dr. Frye did consider immune issues, and noted that children of their age do not have well developed immune systems, and are actually more susceptible to mold exposures. Frye T. 17:2-22; 18:1-2. Dr. Frye, as treating doctors are entitled to do, relied on the patient history to inform her of the presence of molds in the subject home. Frye T. 21:1-21.

Dr. Frye, even in 2002, was not speculating about mold problems; she had performed research. She did not attempt to apply any "safe threshold" for mold as none exists, Frye T. 23:10-22; and she fully understood that mold growing in a closed space (home) was distinct from outdoor molds, Frye T. 24:1-21; 25: 1-20. Dr. Frye already knew that the mold *Aspergillus* produces toxins (mycotoxins), and even without that, the mold *Aspergillus* causes health effects

itself. Frye T. 26:18-22; 27:1-22; 28:1-13. Dr. Frye knew that allergens can cause infections, through bacterial infection of mucous secretions caused by the allergens. Frye T. 32:13-19. Dr. Frye also observed that repeat treatments with antibiotics for such infections was not successful, indicating a compounding factor such as the mold exposures. Frye T. 33:2-22; 34:1-8; 45:3-20 While it is true that Dr. Frye did not consider an autoimmune disease in A.K. as a cause, it would not matter as mold causes this disorder as well, see below; K.K. was never reported to have such a disorder.

Dr. Frye, in her medical records, and by deposition, consistently held that the mold exposures to *Aspergillus* and *Stachybotrys* at least contributed to the illness of both children, and she renders such opinion to a degree of medical certainty and more likely than not. Frye T. 44:2-13; 51:1-22; 52:2-10. Under every rule of this Circuit and *Daubert*, her differential diagnosis is admissible.

Defendants assert that Dr. Frye based her opinion "solely upon the alleged exposure reported by Susan Kristensen." Def. Mem. In Support at 15. This is extremely misleading and untrue. Dr. Frye based her opinions upon months of treating the children and observing their symptoms. Then, based on that, and upon information provided by the Mother that the children had been exposed to *Aspergillus* and *Stachybotrys* in the home, a true statement, researched these molds in infectious disease manuals and medical literature, matched the symptoms and causation information to what she saw in the children and came to her own conclusions. See above. To argue that the treating doctor could not rely on the patient histories and information provided by the parents is without merit.

There is nothing in Dr. Frye's deposition indicating that Dr. Frye failed to consider

medical history at the time of her diagnosis. Dr. Frye did consider alternatives, and excluded other forms of infections and immune issues because the children did not respond to antibiotics in the normal fashion. *Supra.* These children were very young, and there was then as remains today little other exposures or causes to exclude. As to K.K. Dr. Frye had her entire treatment history, and as to Alex she had his medical history since age two. *Supra.* At this age and stage of treatment, there is very little in the way of other causes to exclude, and even if the Defense experts conjure up something at trial, the issue remains a debate among experts, not a *Daubert* issue. While Defense counsel can be given credit for showing that he can confuse a treating doctor on the fine points of legal causation, that goes to credibility, not causation. When the dust settled at the deposition, Dr. Frye stood by her conclusion independently reached in May 2002 and she affirmed that opinion to a degree of more likely than not. *Supra.* A treating doctor is not required to exclude every possible cause in the world:

> A reliable differential diagnosis typically, though not invariably, is performed after 'physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,' and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Westberry at 178 F.3d at 262-263. This is exactly what Dr. Frye did.

For their sole factual basis to argue that Dr. Frye failed to consider other alternatives, Defendants point to a later diagnosis of autoimmune disease (unspecified) by a Doctor Salisbury. Defendants are certainly free to bring in Dr. Salisbury to render his opposing views, and be cross examined on that opinion, if it is opposing. It is unlikely that Dr. Salisbury could oppose Dr. Frye's conclusions, however, because there is no question in the medical and governmental

community that mold and mold byproducts exposure can cause immune system problems.[27] Thus, accepting Dr. Salisbury's later diagnosis at face value, it is not necessarily inconsistent with Dr. Frye's opinions.

DOCTOR ANDREW ELGORT'S OPINION IS RELEVANT

Dr. Elgort is a licensed clinical psychologist (T. 7:16-17) who rendered psychological treatment services to K.K. He is a treating doctor, not a retained expert; however, he is not a

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[27]/ "Many symptoms and health effects attributed to inhalation of mycotoxins have been reported including: . . .immune system suppression." EPA at 42. "Although a great deal of attention has focused on the effects of bacterial and fungi mediate by allergic responses, these microorganisms also cause nonallergic responses. . .In vitro and in vivo studies have demonstrated adverse effects-including immunotoxic . . . responses after exposure to . . . molds, or their products." IOM at 7. "Studies of health associated with exposure to bacteria and fungi show that respiratory and other effects that resemble allergic responses occur in non-atopic persons. In addition, outcomes not generally associated with an allergic response- including . . . suppression of the immune response . . . have been reported in people who live or work in building that have microbial growth." IOM at 125. "Exposure to microorganisms and their products can irritate mucous membranes . . .and lead to inflammation via an immune response. Such immune responses are important in normal host defenses, but chronic or excessive release of inflammatory mediators can cause damage to the lung . . ." (Found here). IOM at 133. "Microorganisms and their toxins can lead to effects on the tissues and cells of the respiratory system. Some of these effects might be mediated by effects on the immune system." IOM at 136. "Inhibition or modulation of immune defenses results from a variety of mycotoxins . . .three groups of mycotoxins are predominantly associated with immunosuppressive toxicity . . . trichothecenes [produced by *Stachybotrys*]. IOM at 151. "Certain common molds can produce metabolites with a wide range of toxic activities such as . . .immune suppressive . . . ." CDC at 20. "Many mycotoxins are immunotoxic . . . most attention are the trichothecenes produced by *Stachybotrys chartarum*." WHO at 18. "The immunosuppressive effects of mycotoxins have been confirmed in experimental animals. Trichothecenes . . . impair immune responses to respiratory virus infection . . . Microbial fragments can . . . cause autoimmune reactions by molecular mimicry, acting as microbial superantigens or by enhancing the presence of autoantigens." WHO at 87. "The immunostimulatory properties of the fungal and bacterial strains typically found in moisture-damaged buildings are synergistically potentiated by microbial interactions during concomitant exposure in vitro." WHO at 89. HUD (identified at note 13) found that "certain molds can cause a variety of adverse human health effects, including allergic reactions and immune responses (e.g. asthma), infectious disease . . . and toxic effects . . . ." HUD at 1.

medical doctor and under both federal and state law, he may not render a causation opinion. *See, Cooper v. Smith & Nephew*, *Inc*., 259 F.3d 194, 198 (4th Cir. 2001). Dr. Elgort may render a diagnosis of K. Kristensen's emotional state at the time of his treatment. He diagnosed K.K. as having "adjustment disorder not otherwise specified." Elgort T. 13:16-25; 14:1-25. He further testifies as to the emotional state of K.K. as of his last visit, where she was "continuing to have behavior problems." Elgort T. 22:12-25. As a practical matter, all of Dr. Elgort's conclusions are contained within his medical records, which come into evidence on their own. There is no challenge to Dr. Elgort's qualifications or methodology. The dispute seems to be over whether Dr. Elgort can appear live to report from his records to the jury.

Contrary to Defense claims, Dr. Elgort is not presented as a causation witness; he will not be asked to render any causation opinion. He will be asked to render his diagnosis and state the emotional condition of K.K. during his visits.

Plaintiffs allege that the entire family suffered an exposure in the home and suffered similar symptoms. The Plaintiff children suffered physical injuries and emotional distress from the home exposure. Then, when the Plaintiff children and family were forced from the home, the children suffered further emotional distress in the loss of all their belongings. This emotional distress of the children was then further compounded by the Mother's complete disability from the mold exposures in the subject home, and then continued as the parents divorced under the unrelenting stress originally induced by the family illnesses in the home. The Plaintiff children are entitled to compensation for their direct injuries and all injuries which flow from such injury. The childrens' emotional condition continued from the original injury at least through 2008 and the parents are expected to testify that it continues to the day of trial.

For these impacts, Dr. Elgort will provide the jury with (1) a diagnosis of adjustment disorder, which is relevant; and that (2) such emotional condition was documented and remained in place in 2008 when he last saw her. Dr. Elgort will not be opining as to the cause of the adjustment disorder. That said, the emotional diagnosis and condition of K.K. is clearly relevant to her emotional distress claim.

CONCLUSION

The proposed opinions (or testimony in the case of Dr. Elgort) of Plaintiffs' experts is based on solid methodology in their respective fields, is the result of proper application of facts and evidence to their conclusions, and is overwhelmingly supported by both governmental and scientific treatises on mold and related damp indoor space health issues. Each opinion is consistent with the holding of *Daubert* admissibility and the expert testimonial evidence outlined by the fourth circuit in *Westberry*. Therefore, the motions to exclude should be denied.

Respectfully submitted,

K.K. and A.K., by counsel

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CERTIFICATE OF SERVICE

I hereby certify that on August 3, 2011 I electronically filed Plaintiffs' memorandum in opposition to Defendants' motion to exclude Plaintiffs experts with the Clerk of the Western District Federal Court, Charlottesville, Virginia using the CM/ECF system which will send electronic copies of the document to Chad Mooney and Ed Dawson, Petty, Livingston, Dawson & Richards, 725 Church Street, Suite 1200, P.O. Box 1080, Lynchburg. Virginia 24505 at cmooney@pldrlaw.com and edawson@pldrlaw.com. There are no other counsel in the case that require hard copy mailing.

_/S/_____
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